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Individual Safety Report
3017763-6-00

d by FDA on 11/16/93

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	or 44 yrs Date of birth: [redacted]	( )female (X)male	200 lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(X) death 4/2/97 (mo/day/yr)
( ) life-threatening
(X) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr): 3/26/97

4. Date of this report (mo/day/yr): 01/08/98

5. Describe event or problem

Notified via manufacturer (mfr.report ##T97-USA-00354-01(-0) of DEATH in a 44 yo w/asthma who was enrolled in study AER-MD-02-000 for AEROBID-M®. On 3/11/97, approx 2 months after commencing study drug, pt was withdrawn from study (cause unk).On 3/26/97,pt presented w/mild RASH & diffuse joint pain (ARTHRALGIA). PE revealed JAUNDICE & borderline COMA; other findings normal.Diagnosed w/HEPATITIS per lab findings & hospitalized.Reportedly pt had H/O alcohol & cocaine abuse & had been taking two TYLENOL q4hrs for about 4 days. MD d/c TYLENOL & prescribed ADVIL® & NAPROSYN®. Later that day, pt became somnolent(SOMNOLENCE) & subsequently diagnosed w/fulminate LIVER FAILURE.Pt was intubated.Kidney US Bx was negative.Investigator reported that etiology was unclear;does not have stigmata of end-stage liver disease. Pt started on MUCOMYST.Hepatitis serologies sent;results pending.On 4/2/97 pt died (cause unspecified). According to investigator, events were serious & unrelated to study drug but could be associated w/pt's prior H/O alcohol & TYLENOL consumption.

6. Relevant tests/laboratory data, including dates

3/26/97 B/P=160/80 3/30/97 ALB=3.3,ETOH=19,ALK-P=672,NH3=194, AMY=318,AST=7010,BUN=27,CPK=115,SCr=1.9,BS=49,LDH=2180, pH=7.3,pCO2=26,pO2=72,PT(INR)=greater than 4.61,PTT=59/30, salicylate & tricyclics=0, TYLENOL=less than 10, TBILI=14

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

alcohol, drug abuse, (prescription & OTC), seasonal & perennial allergic rhinitis 1987-ongoing, heartburn 1985, sinus headaches 1976, asthma 1987, cigarette abuse (2 packs/day), vasectomy, lipoma removed from Rt abdominal wall 12/95, no H/O prior liver disease, recent travel, or family H/O liver disease, no use of any other drugs which (See Sect.C.10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TYLENOL Analgesic Unknown
#2 AEROBID-M (FLUNISOLIDE) INHALER SYSTEM

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 2 tabs, q4hrs, po	#1 3/97; 4 days
#2 unknown dose, per oral	#2 1/9/97-3/11/97

4. Diagnosis for use (indication)

#1 unknown
#2 asthma

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 (X) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2 unknown	#2 unknown

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

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10. Concomitant medical products and therapy dates (exclude treatment of event)

ADVIL®(Ibuprofen) & NAPROSYN®(Naproxen)
Sect.B.7 con't: could be hepatotoxic,drank at least 4-5 alcoholic hard liquor drinks per day, cocaine abuse but no IV drug abuse

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

( ) foreign
(x) study
( ) literature
( ) consumer
(x) health professional
( ) user facility
( ) company representative
( ) distributor
(x) other: manufact

4. Date received by manufacturer (mo/day/yr): 01/02/98

5.
(A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

DEATH
COMA
JAUNDICE
RASH
LIVER FAILURE
HEPATITIS
SOMNOLENCE
ARTHRALGIA

9. Mfr. report number: 0913047A

E. Initial reporter

1. Name, address & phone #

Forest Laboratories, Inc.
909 Third Avenue
New York, NY 10022-4731
212-421-7850

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes ( ) No	manufacturer	(X) Yes ( ) No ( ) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.